IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIAN JOSEPH GREF, **Plaintiff,** **v.** **AMERICAN INTERNATIONAL INDUSTRIES, *et al.*,** **Defendant.**	**No. 1:20-cv-005589-GBD-VF** **DECLARATION OF NATHAN A. HUFF**

I, Nathan A. Huff, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am a partner at the law firm K&L Gates LLP, attorneys for nonparty Northwell Health, Inc. ("Northwell").

2. I submit this Declaration pursuant to Rule 45(d)(3) of the Federal Rules of Civil Procedure in connection with Northwell's February 22, 2023 letter to the Court, which supplements the record regarding Northwell's Motions to Modify the nonparty subpoenas ("Nonparty Subpoenas") served on Northwell by Defendants American International Industries ("AII") and Whittaker, Clark & Daniels, Inc. ("WCD") (collectively, the "Defendants").

3. The Court ordered Northwell to supplement the record with certain information from the bench at the February 8, 2023 oral argument on Northwell's Motions to Modify, and also invited Northwell to submit additional materials.

4. Accordingly, in support of the letter—and as referenced therein—Northwell submits the following supplementary documents, which I declare under penalty of perjury are true and correct copies of the named documents:

Exhibit	Name (Description)
Background Information/Documents	
A.	*Mesothelioma Associated with the Use of Cosmetic Talc*, Ronald E. Gordon, PhD, Maya Alexandri, JD, Kristin Bevilacqua, MPH, and Jacqueline Moline, MD, Journal of Occupational and Environmental Medicine, Vol. 62 No. 1, Jan. 2020. (The authors noted that "among women, occupational exposure explains less than half of malignant mesothelioma cases." They concluded that "exposure to asbestos-contaminated talcum powders can cause mesothelioma. Clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma.")
B.	Consolidated Excerpts from Deposition Transcripts of Dr. Jacqueline Moline (showing that, since the M.D.N.C's *Bell* order, counsel for AII has repeatedly invoked Ms. Bell's identity and PHI in cases to which Ms. Bell is a stranger)
C.	Excerpt from Bloomberg Law asbestos litigation analytics (showing that the same parties to the *Gref* litigation have been involved in hundreds of asbestos cases around the country)
D.	Excerpt from Thomson Reuters asbestos litigation analytics (showing that the lawyers for AII and WCD have been involved in hundreds of asbestos cases around the country)
Pathway 1: The Common Rule	
E.	45 C.F.R. § 46.101 (subjecting to the Common Rule any research that is "subject to regulation by any Federal department or agency" and mandating that institutions comply therewith)
F.	45 C.F.R. § 46.103(a) (requiring an institution engaged in federally funded research to provide a "written assurance" confirming it will comply with the requirements of the Common Rule, which must be "executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy . . . in such form and manner as the department or agency head prescribes")
G.	Northwell Health, Federalwide Assurance (FWA) #00002505 (written agreement—in effect at time of IRB application for the Article—pursuant to which Northwell agrees to provide Common Rule protections to all research "regardless of the source of support;" signed by Northwell's Executive Vice President of Research; approved and signed by an HHS Approving Official)
H.	HHS Office for Human Research Protections PowerPoint (confirming that FWAs "[n]eed to include a 'signatory official' who has the authority to commit the entire institution/organization named in the FWA to a legally binding agreement")
I.	Screen Capture – HHS Website (Office for Human Research Protections), publicly available at https://ohrp.cit.nih.gov/search/FwaDtl.aspx (screen capture showing that HHS advertises to the public that Northwell maintains an FWA)

J.	45 CFR § 46.111 (setting forth requirements for IRB approval of research, including provisions for the protection of privacy and confidentiality)
K.	45 CFR § 46.116(f) (providing IRB requirements for authorizing waiver of informed consent requirement for conducting research)
L.	IRB Approval, Northwell Health Feinstein Institute for Medical Research, IRB No. 18-0225, FWA #00002505 (Northwell's IRB approval of the proposed research for the Article and confirming it meets the regulatory requirements for a waiver of the informed consent requirement)
Pathway 1: HIPAA Privacy Rule	
M.	45 C.F.R. § 164.502(a) ("A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.")
N.	45 C.F.R. § 160.103 "Covered entity means: (1) A health plan[;] (2) A health care clearinghouse[;] [or] (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." "Health information means any information . . . whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider[;] and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual." "Protected health information means individually identifiable health information: (1) . . . that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium. (2) Protected health information excludes individually identifiable health information: . . . (iv) Regarding a person who has been deceased more than 50 years."
O.	*Public Still Must Be Kept Private Under HIPAA*, Glory Francke, Adam H. Greene, and Rebecca L. Williams, Healthcare Advisory, May 16, 2017, Davis Wright Tremaine LLP. (article describing an OCR enforcement action against a health system that disclosed PHI that had already been publicly disclosed to the media ("Public knowledge is no excuse: Even if someone (such as the media) knows an individual was a patient, a provider cannot release additional PHI or even confirm that the individual was a patient without a valid basis under HIPAA."))
P.	*Texas Health System Settles Potential HIPAA Disclosure Violations*, HHS Press Release, (May 10, 2017). (HHS Press Release describing $2.4 settlement with medical practice after it disclosed the name of a patient, even though the patient's status had already been disclosed in the media.)

Q.	45 C.F.R. § 164.514 (a) (authorizing Northwell to use in its research de-identified PHI, i.e. information "that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.") (c) ("A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that: (1) . . . The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and (2) . . . The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.")
R.	HIPAA Authorization: Betty Bell (Plaintiff in *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. July 2021)) (Example of HIPAA authorization used in asbestos litigation, including automatic expiration after two years)
S.	HIPAA Authorization: Doris Jackson, the plaintiff featured in Defendants' response brief (ECF 279 p 25) (Example of HIPAA authorization used in asbestos litigation, specifying that authorization will automatically "expire one year from the date signed or at the conclusion of this litigation")
Pathway 2: Undue Burden	
T.	Order, *Peninsula Pathology Associates v. American International Industries*, Case No. 4:22-mc-1 (E.D. Va. Dec. 23, 2022) ("[W]hen assessing the burden to the recipient, courts should consider, among other things, the financial cost of producing the information as well as 'other cognizable burdens,' such as (1) the impact of production on privacy or confidentiality interests; (2) the interests—including business interests—of the recipient and others who might be affected; and (3) whether the subpoena is overbroad and would require 'tailoring' by the nonparty." (quoting *Va. Dep't of Corr. V. Jordan*, 921 F.3d 180, 189-90 (4th Cir. 2019)))
U.	*In re Terrorist Attacks on Sept. 11, 2001*, 523 F. Supp. 3d 478, 489 (S.D.N.Y. 2021) (citing *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998)) ("concern for the unwarranted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs" in a Rule 45 inquiry))
V.	*Trellian Pty, Ltd. v. adMarketplace, Inc.*, No. 19CIV5939JPCSLC, 2021 WL 363965, at *2 (S.D.N.Y. Feb. 3, 2021) ("Courts thus afford 'special weight to the burden on non-parties of producing documents to parties involved in litigation,'") (quoting *Travelers Indem. Co. v. Metro. Life Ins. Co.*, 228 F.R.D. 111, 113 (D. Conn. 2005))
W.	*MacNamara v. City of New York*, No. 04CIV.9612(KMK)(JCF), 2006 WL 3298911, at *15 (S.D.N.Y. Nov. 13, 2006) ("However, courts also give special weight to the burden on non-parties of producing documents to parties involved in litigation.")

X.	Northwell Health Human Research Protection Program Policies and Procedures, Apr. 20, 2021 *available at* https://www.northwell.edu/sites/northwell.edu/files/2021-05/HRPP-Policies-and-Procedures-FINAL-2021.pdf. ("Northwell Health has a Federal Wide Assurance (FWA) . . . which assures the Department of Health and Human Services (DHHS) that it will follow procedures to assure the protection of all human subjects involved in research projects. The assurance is a formal agreement between the Office for Human Research Protections (OHRP) and the authorized Institutional Official for Northwell. This assurance applies to all research involving human subjects, regardless of source of funding or support, conducted at Northwell Health, as well as to research conducted elsewhere by physicians, students, staff, or other representatives of Northwell in connection with their institutional responsibilities.")
Y.	Transcript Excerpt, *Peninsula Pathology Associates v. American International Industries*, Dec. 16, 2022. Full text available at ECF 305-3. (Lead counsel for AII asserting that "[t]alc litigation started after 2014 with the Gordon/Millette article.")
Z.	*Asbestos in Commercial Cosmetic Talcum Powder as a Cause of Mesothelioma in Women*, Ronald E. Gordon, Sean Fitzgerald, James Millette, International Journal of Occupational and Environmental Health, Vol. 20, No. 4 (2014). ("This brand of talcum powder contained asbestos and the application of talcum powder released inhalable asbestos fibers. Lung and lymph node tissues removed at autopsy revealed pleural mesothelioma . . . Previous research suggests that . . . mesothelioma may be directly attributed to the use of talcum powder contaminated with asbestos . . . .")
AA.	Excerpt from Deposition Transcript of Alan Feingold, M.D., *Weiss v. Albertsons Companies, Inc.*, No. CV2021-090946 (Ariz. Super. Ct. Jan. 24, 2023) (Dr. Feingold—an expert for AII in the *Gref* litigation—testifying that subjects in medical and scientific literature are de-identified to protect their privacy rights and because "if people thought they might be identified they might be less willing to participate in that study," and refusing to talk about the *Bell* case without permission from Lathrop, the same firm representing AII in *Gref*)
BB.	Excerpt from Deposition Transcript of Victor Louis Roggli, M.D., *Morrison v. Alfa Laval, Inc.*, No. BC441029 (Cal. Super. Ct. Feb. 3, 2011), 44:25-45:7 ("I also have objection to it because in – personally, because in the 25 years that I've been testifying as an expert in federal and state courts these requests go far beyond anything that have been requested of myself or my colleagues that I'm aware of, and I don't think that they are appropriate investigation into scientific merit or arguments that are made in the scientific literature . . . .")
CC.	Excerpt from Deposition Transcript of Gregory B. Diette, M.D., *Lopez v. Brenntag North America, Inc.*, No. 2017-860222 (M.D.L. Pre-Trial Judge June 19, 2020) (expert witness testifying as to the importance of protecting the identity of the 33 subjects whose medical data is featured in the 2020 peer-reviewed article)

DD.	Excerpt from Deposition Transcript of Theresa Swain Emory, M.D., *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. Oct. 1, 2020) (Testifying that "revealing anonymized human subjects would jeopardize [Dr. Moline's] medical license")

I declare under penalty of perjury under the laws of the United States of America (28 U.S.C. § 1746) that the foregoing is true and correct.

Executed: February 22, 2023
Morrisville, North Carolina

Nathan A. Huff